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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/612,055	07/07/2000	Joseph H. Sklar	SKLAR-21	6809

7590 01/16/2003

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EXAMINER

BUMGARNER, MELBA N

ART UNIT

PAPER NUMBER

3732

DATE MAILED: 01/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/612,055

Applicant(s)

SKLAR, JOSEPH H.

Examiner

Melba Bumgarner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-13 is/are pending in the application.
- 4a) Of the above claim(s) 9-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 31 October 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 9-13 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 9 is a method for securing at least one ligament to a bone within a new bone tunnel adjacent to an old bone tunnel and claims 10-13 are a system for securing at least one ligament to a bone. The invention originally claimed a ligament shim and a method for securing at least one ligament to a bone within a bone tunnel.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 9-13 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Drawings

1. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on October 31, 2002 have been approved. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 3-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how the "slightly oversized" dimension is determined in all the claims, particularly the configurations for claims 6-9, and what is "a portion" of the interstitial space to which the cross-sectional area is related. In claim 6, it is unclear whether the shim is intended to be placed in the interstitial space or between the first portion and second portion of the at least one ligament, and if it is the latter, the cross-sectional area relative to the interstitial space is not of significance. In claim 8, it is unclear whether the shim is intended to be placed in the interstitial space or between the first, second, third, and fourth portions of the at least one ligament, and if it is the latter, the cross-sectional area relative to the interstitial space is not of significance.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 2 and 3 are rejected under 35 U.S.C. 102(e) as being anticipated by Harwin (5,876,455). Harwin discloses ligament shim 10 for insertion into a bone tunnel

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comprising a body having a first end and a second end, a longitudinal axis from the first end to the second end and at least two walls 10', 10" extending substantially parallel to the axis; a portion of the body defining a cross-sectional area in a plane substantially perpendicular to the axis; and a rounded bearing surface formed at the first end as seen in figure 3. The size of the portion of the body is held to be a matter of intended use and the relative term "slightly oversized" is broad in that is defined in terms of the varying size of human anatomy; therefore, not given patentable weight. Harwin shows the shim is placed in the interstitial space 4, the shim will hold the at least one ligament against a wall of the bone tunnel (figure 3, column 2 lines 45-53). Harwin shows a method for securing at least one ligament to a bone within a bone tunnel, the bone tunnel having a transverse cross-sectional area greater than a transverse cross-sectional area of the ligament (figure 3), the method comprising inserting the at least one ligament into the bone tunnel; attaching the at least one ligament to the bone; and inserting a ligament shim 10 into the bone tunnel so as to occupy a portion of the transverse cross-sectional area of the bone tunnel (column 1 lines 28-40, column 2 lines 32-53).

6. Claims 4-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Kim (6,355,066). Kim discloses ligament shim 10 for insertion into a bone tunnel comprising a body having a first end and a second end 14, 12, a longitudinal axis from the first end to the second end and at least two walls extending substantially parallel to the axis; a portion of the body defining a cross-sectional area in a plane substantially perpendicular to the axis; and the body having a tow hole 22 therethrough between the first and second end, the hole extending substantially orthogonal to the longitudinal axis; the

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shim is positionable within the bone tunnel by pulling a suture 102 inserted through the hole (column 6 line 27). The size of the portion of the body is held to be a matter of intended use and the relative term "slightly oversized" is broad in that is defined in terms of the varying size of human anatomy; therefore, not given patentable weight. Kim shows the ligament shim 10 comprising a first pair of opposing arcuate surfaces 19, 20 being formed by the at least two walls, the surfaces curving inwardly toward one another and being formed substantially along the axis, when the shim is positioned between a first portion of the at least one ligament and a second portion of the at least one ligament in the bone tunnel, the shim will conform to the portions and urge the portions against the wall of the tunnel (column 1 line 49). Kim shows a second pair of opposing arcuate surfaces, the second pair of surfaces curving outwardly away from one another, formed substantially along the axis, and conforms to the wall of the bone tunnel (figure 3).

7. Claims 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Luscombe et al. (5,683,418). Luscombe et al. disclose a shim 100 comprising a body having a first end and a second end, a longitudinal axis from the first end to the second end, and at least two walls extending substantially parallel to the axis; a portion of the body defining a cross-sectional area in a plane substantially perpendicular to the axis; and the body having a tow hole 102 therethrough between the first end and the second end, the hole extending substantially orthogonal to the axis. Patentable weight is not given to the intended use of the shim.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beck, Jr. et al. (5,632,748). Beck, Jr. et al. disclose a ligament shim 16 comprising a body 23 having a first end 20 and a second end, a longitudinal axis from the first end to the second end, and at least two walls extending substantially parallel to the axis; a portion of the body defining a cross-sectional area in a plane substantially perpendicular to the axis; and a first pair of opposing arcuate surfaces being formed by the at least two walls, the surfaces curving inwardly toward one another and being formed substantially along the axis; however, they do not show a second pair of opposing arcuate surfaces formed by the at least two walls with the surfaces curving inwardly toward one another. It is held to be an obvious matter of choice to one of ordinary skill in the art as to the specific number of arcuate surfaces curving inwardly and the specific use of the surfaces. The specific number of arcuate surfaces is not critical to the claimed invention.

Response to Arguments

10. Applicant's arguments filed October 31, 2002 have been fully considered but they are not persuasive. As to claim 2, a method for securing at least one ligament to a bone within a bone tunnel, the steps are shown in the prior art. There are no limitations to

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support applicant's remark that the claimed invention includes another fastener to secure the ligament to the bone. As to claim 3, the prior art shows the structural limitations of the claim. Applicant's arguments with respect to claims 4-8 have been considered but are moot in view of the new grounds of rejection.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melba Bumgarner whose telephone number is 703-305-0740. The examiner can normally be reached on Mon-Fri.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Melba Bumgarner



KEVIN SHAVER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

1/19/03